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K082784

CHAPTER 5. 510(K) SUMMARY

This 510(k) summary of safety and effectiveness for **Jumao Manual Wheelchair** is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Table 5-1 General Information

Applicant:	Danyang Jumao Healthcare Equipment Co., Ltd.
Address:	No.89 Shuangfeng Road, Jiepai town, Danyang, Jiangsu, P.R.China
Contact Person:	Qing Wang
Telephone:	(86 511)- 86379811
Email:	kenwqing@gmail.com
Date of Preparation:	July 28, 2008
Device Name:	JUMAO MANUAL WHEELCHAIR
Classification Name:	Manual Wheelchair
Device Class:	Class I
Product Code:	IOR
Classification Panel	Physical Medicine
Type of submission	Traditional 510K

Intended use:

The **Jumao Manual Wheelchair** is intended for medical purposes to provide mobility to persons restricted to a seated position.

Indications for Use:

The **Jumao Manual Wheelchair** is intended for medical purposes to provide mobility to persons restricted to a seated position. **Jumao Manual Wheelchair** is not designed, sold, or intended for use except as indicated.

Device Description

The Jumao Manual Wheelchair is an indoor/outdoor wheelchair that has a base with four-wheels with a seat. The device can be disassembled for transport and it is foldable easily. Both the back and seat upholstery material is the same resistance-ignitability fabric.

All device functions, scientific concepts, significant physical and performance characteristics (i.e. device design, materials, physical properties, etc.) are identical to the design and manufacture described in Predicate Device.

Predicate Device:
Universal Wheelchair by Graham-Field Health Products, Inc. (Formerly Everest & Jennings), 510(k) K930411.

Substantial Equivalence Information:

Technological/Safety Characteristics:
The **Jumao Manual Wheelchair**'s technological and safety characteristics are identical to those described in the Predicated Device. The detailed comparison table is included in Chapter 10.

Performance Data:
The **Jumao Manual Wheelchair**'s performance is shown to comply with the relevant ISO 7176 standards, identical to those described in the Predicated Device.

Conclusion:
The data submitted in this 510(K) Premarket Notification supports the finding that this device is substantially equivalent with respect to the intended use, technology, functionality, and safety features to the legally marketed Predicate Device. Therefore, we believe that this device meets the requirement for a "Substantial Equivalence" decision in accordance with the 510(K) guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 7 2008

Danyang Jumao Healthcare Equipment
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, MN 55313

Re: K082784
Trade/Device Name: Jumao Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: September 22, 2008
Received: September 23, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CHAPTER 4. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **Jumao Manual Wheelchair**

Indications for Use:

The **Jumao Manual Wheelchair** is intended for medical purposes to provide mobility to persons restricted to a seated position.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k082784